FDA Alerts of Perrigo's Voluntary Albuterol Inhaler Recall

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The United States (US) Food and Drug Administration (FDA) is alerting healthcare professionals (HCPs) and patients of a voluntary recall of all unexpired albuterol sulfate inhalation aerosol manufactured by Catalent Pharma for Perrigo, due to possible clogging of the inhaler resulting in patients not receiving enough or any medicine. This recall is to the retail level. The FDA urges patients to continue using the inhaler they have on hand.

The albuterol inhaler delivers medication into the body through the airway and lungs, where it opens the airways to treat asthma and other conditions, such as chronic obstructive pulmonary disease (COPD). Patients could experience health risks if their rescue albuterol inhaler malfunctions and does not relieve symptoms in an emergency situation.

The FDA is advising patients to:

- immediately seek emergency care if needed;
- use their Perrigo inhaler they have on hand, as needed and as directed by a doctor;
- have extra inhalers or an alternative treatment available in case of malfunction, as some of these recalled inhalers stop working after several uses; and
- contact their HCP or pharmacist with questions.

FDA reminds HCPs and patients that albuterol inhalers are available through additional manufacturers.

Perrigo informed the FDA it had received several thousand complaints about its product. Most of the complaints were for clogging and failure to dispense enough medicine. The manufacturer of Perrigo’s albuterol inhaler, Catalent, stopped producing and distributing the albuterol inhaler products on August 21, 2020 and is currently investigating the malfunction.

The agency asks HCPs and patients to report unexpected side effects or quality problems associated with albuterol inhalers to FDA’s MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.